510(k) Summary: Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Angioslide Ltd.

Establishment Registration Number: Not Yet Assigned

MAR 2 8 2010

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Date Summary Prepared: March 1, 2010

Name of Device: Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature

Classification Name: Percutaneous Catheter

Device Classification:

Classification: II

Classification Panel: Cardiovascular

Regulation Number: 21 CFR 870.1250

Product Code: LIT, DQY

Predicate Devices:

1. AgilTrac .035 Peripheral Dilatation Catheter (K023320)
2. ATB Advance PTA Balloon Catheter (K052036)
3. Spider FX Embolic Protection Device (K063785)

510(k) Summary: Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature (K090364)

Device Description:

The Angioslide eXtra™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is a single-use disposable over-the-wire co-axial dual lumen catheter with a foldable balloon near the distal tip. The balloon catheter consists of the balloon located near the distal atraumatic soft tip, the telescopic shaft and the handle.

One lumen is used for inflation of the balloon and is accessed via the inflation port. The other lumen, starting at the guidewire port, allows access to the distal tip for guidewire insertion (max. 0.035"). The balloon has two radiopaque markers for positioning the balloon relative to stenosis. The radiopaque markers indicate the dilating section of the balloon and help in balloon placement. The balloon is designed to provide an inflatable segment of known diameter and length at specified pressure.

The shaft comprises the outer shaft and the inner shaft. The distal end of the balloon is connected to the inner shaft and the proximal end of the balloon is connected to the outer shaft. The inner shaft is connected to the pulling rod and the outer shaft is connected to the handle body. The pulling rod lock locks the handle body and the pulling rod together. The distal end of the balloon is folded inwards towards the proximal end of the balloon, by unlocking the pulling rod lock counter-clockwise and retracting the pulling rod. The inward-folding of the balloon forms a cavity and allows for collection of embolic material.

Indications for Use:

The Angioslide eXtra™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature is indicated for peripheral transluminal angioplasty and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

The Angioslide eXtra™ PTA Balloon Catheter is not intended for use in the renal, cerebral, coronary or carotid vasculature.

Technological Characteristics:

The Angioslide eXtra™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter is an over the wire co-axial dual lumen catheter with a foldable balloon located near the distal atraumatic soft tip. The catheter is compatible with 0.035" guidewire.

The technological characteristics of the eXtra™ PTA Balloon Catheter are substantially equivalent to those of the AgilTrac .035 Peripheral Dilatation Catheter (K023320), the ATB Advance PTA Dilatation Catheter (K052036), and the Spider FX Embolic Protection Device (K063785).

Summary of Bench Testing:

In vitro bench testing of the Angioslide eXtra™ PTA Balloon Catheter was conducted in accordance with Angioslide's Risk Analysis and all applicable FDA Guidance documents and ISO standards, including:

ISO 10555-1 – Sterile, Single Use Intravascular Catheters- Part 1: General Requirements

ISO 10555-4 – Sterile, Single Use Intravascular Catheters- Part 4: Balloon Dilatation Catheters

FDA Guidance – Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems , January 13, 2005 (http://www.fda.gov/cdrh/ode/guidance/1545.html)

FDA Guidance – Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions, February 15, 2008 (http://www.fda.gov/cdrh/ode/guidance/1658.html)

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The following bench tests were conducted. All bench testing, unless otherwise specified, was conducted using finished devices which were double-sterilized by the final validated sterilization process.

- Catheter Dimensional Verification
- Balloon Burst
- Balloon Compliance
- Catheter Inflation / Deflation Time
- Balloon Fatigue
- Corrosion
- Leakage
- Bond Tensile Strength (all bonds)
- Distal Bond Peel Strength
- Marker Radiopacity
- Simulated Use including; Guidewire Compatibility, Deployment and Retraction, Kink Resistance, Advancement Force, Retraction Force, Tortuous Anatomy Compatibility
- Introducer Sheath Compatibility
- Catheter Flow Characteristics
- Comparative Capture Efficiency

Biocompatibility Testing:

The Angioslide eXtra™ Percutaneous Transluminal Angioplasty catheter is an Externally Communicating Device, which contacts circulating blood for the Limited Contact Duration (< 24 hours).

Biocompatibility testing of the Angioslide eXtra™ balloon catheter was performed on finished and sterilized devices in accordance with the ISO-10993-1, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing," as specified in the FDA Blue Book Memorandum #G95-1.

All testing documented below was conducted in accordance with the provisions of the FDA GLP regulations 21 CFR Part 58. All the tests passed.

- Cytotoxicity per EN ISO10993-5
- Sensitization – Murine LLNA per EN ISO10993-10
- Irritation Test -ISO Intracutaneous per EN ISO10993-10
- Acute Systemic Toxicity – ISO Systemic Toxicity study per EN ISO10993-11
- USP Pyrogen study – material mediated per EN ISO10993-11
- Hemocompatibility - ASTM Hemolysis per ASTM F756-00 and EN ISO10993-4
- Hemocompatibility – C3a Complement Activation Assay per EN ISO10993-4
- Hemocompatibility –SC5b-9 Complement Activation Assay per EN ISO10993-4
- In Vivo Thromboresistance Study in the Dog – Femoral Artery

Summary of Animal Testing:

A chronic GLP study was conducted to evaluate the safety and performance of the Angioslide eXtra™ PTA Balloon Catheter compared to an appropriate control I. The objective of the study was to demonstrate safety and performance of the eXtra™ PTA Balloon Catheter when used for peripheral percutaneous transluminal angioplasty (PTA) and post-stent dilatation in an *in vivo* porcine model. Safety of the test and control articles was assessed by the study pathologist via gross and microscopic evaluation post-procedure, while functional performance of the test and control articles was assessed by

investigators during PTA and post-stent dilation. The results of this study demonstrated that the safety and performance of the Angioslide eXtra™ PTA Balloon Catheter was substantially equivalent to that of the control article when used in an *in vivo* model.

Summary of Clinical Testing:

Two clinical studies were conducted to demonstrate safety and efficacy of the Angioslide eXtra™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with an Embolic Protection/Capture Feature. The Multi-Center Studies for Lower Extremity Angioplasty with DEbris Removal (MC-LEADER and MC-LEADER Supplemental) were prospective, multi-center (three and two centers respectively, outside of the US), non-randomized, single arm studies. The objective of the studies was to demonstrate safety and efficacy of the Angioslide eXtra™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with an Embolic Protection/Capture Feature when used for lower extremity percutaneous transluminal angioplasty, and embolic debris capture. The studies were conducted under similar protocols for the purpose of pooling the data to support the evaluation of a statistically powered safety hypothesis. The endpoints for each individual study included; acute device success, acute procedural success (<50% residual stenosis), adverse event rates, clinical success at 30 days (ABI and RB improvement), and target vessel revascularization at 12 months (MC-LEADER only). The endpoints evaluated for the pooled clinical data included; target vessel revascularization at 30 days, serious adverse event rate, acute device success, acute procedural success, and acute distal embolization rate. The results of the MC-LEADER and MC-LEADER Supplemental Studies met performance goals derived from historical literature describing PTA performance.

Substantial Equivalence:

Non-clinical and clinical evaluation demonstrated substantial equivalence of the eXtra PTA Balloon Catheter with its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 3 2010

AngioSlide, LTD
c/o Dr. Elisa Harvey
Cardiomed Device Consultants
18905 Celebrity Lane
Sandy Spring, MD 20860

Re: K090364
eXtra PTA Balloon Catheter with Embolic Capture Feature
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: January 29, 2010
Received: January 29, 2010

Dear Dr. Harvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090364

Device Name: eXtra™ Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter with Embolic Capture Feature

Indications for Use:

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Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090364